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09/989,388	11/21/2001	Wataru Morikawa	MORIKAWA4A	1349

EXAMINER	
HARRIS, ALANA M	

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1643	

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BROWDY AND NEIMARK, P.L.L.C.  
ATTORNEYS AT LAW  
SUITE 300  
624 NINTH STREET, N.W.  
WASHINGTON, DC 20001-5303

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/989,388

Applicant(s)

MORIKAWA ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 1-5 are pending.  
Claim 5 has been added.  
Claims 1-5 are examined on the merits.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,288,489 (February 22, 1994/ IDS reference AA). U.S. Patent #5,288,489 discloses a Lys-Lys binding site I which is a plasminogen fragment consisting of Kringle 1 to Kringle 3 which is derived from glu-plasminogen by limited proteolysis, catalyzed by plasmin, whereby a peptide fragment is cleaved from the amino terminal domain, see column 8, lines 45-65. "[T]he glu-plasminogen is the naturally occurring form of plasminogen", see column 8, lines 45 and 46. The patent also discloses that the mini-plasminogen is derived from either glu- or lys-plasminogen catalyzed by pancreatic elastase, see column 8, lines 52-58.

Although patent '489 does not specifically recite the molecular weight, lack of glycosylation, heparin binding activity and inhibiting tumor metastasis and tumor growth

these limitations would be inherent qualities of the recovered compound, which consists of the Lys-Lysine binding site I.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,288,489 (February 22, 1994/ IDS reference AA), and further in view of U.S. Patent number 6,566,098 B1 (filed June 7, 1995) is maintained.

Applicants argue the claimed invention lies in the Lys-Lys binding site I and the specific plasminogen fragment has the properties claimed in sections a.-d. listed in claim 1, see page 9 of the Remarks submitted October 4, 2006. Applicants further arguments submitting while patent '489 discloses the claimed fragment the '489 patent does not teach fragments subjected to heparin affinity chromatography, see page 7, last sentence before 1<sup>st</sup> full paragraph. These points of view and arguments have been carefully considered, but found unpersuasive.

While the primary reference does not describe the production of the claimed product using the methods identical to those recited in the claims, the recitation of a process limitation is not viewed as positively limiting the claimed product absent a showing that the process of making the molecule imparts a novel or unexpected

property to the claimed product. Equivalent products may be obtainable by multiple routes. The burden is placed upon Applicants to establish a patentable distinction between the claimed product and prior art's. The compound is the same and as Applicants have note "[t]he fact...the fragment is prepared by heparin affinity chromatography is not an essential feature" does not materially affect the product itself, see page 9 of the Remarks.

The patent teaches "...a fragment consisting of the proenzyme domain of plasminogen with a single attached kringle is generated, the remaining 4 kringles and intervening peptides having been separated.", see column 8, lines 52-58. The recovered fragment encompasses the Lys-Lysine binding site I, see column 8, lines 47-65. Patent '489 does not teach the fragments have been subjected to heparin affinity chromatography for selecting heparin-binding fractions.

However, U.S. Patent number 6,566,098 teaches a one-step purification process of hepatocyte growth factor (HGF) based on heparin affinity chromatography. "HGF resembles plasminogen in that it possesses characteristic kringle domains.", see column 1, lines 42-48; and column 7, lines 17-26. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to implement this mode of separating kringle fragments. The separation in itself implies fractions of fragments were generated and these fractions of fragments would bind heparin. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both patents to fractionate plasminogen of patent '489 in order to arrive at active fragments of the molecule for

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therapeutic use, as well as to further define the molecule for therapeutic, enzymatic and or catalytic activity, see Patent '489, bridging paragraph of columns 2 and 3; columns 10-14; Patent '098, see column 7, lines 34-60; column 32, lines 9-28.

Applicants have submitted not evidence that the plasminogen fragments instantly claimed are absent from the product taught in the primary reference, patent '489 and absent evidence to the contrary one of ordinary skill in art would conclude the teachings of both patents read on the claims.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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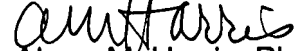
7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.

25 August 2007